the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''Do not use if you have ear drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy; consult a doctor.''

(2) ''Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor.''

(3) ''Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor.''

(4) ''Avoid contact with the eyes.''

(d) *Directions.* The labeling of the product contains the following statement under the heading ''Directions'': FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.

(e) *Optional wording.* The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[51 FR 28660, Aug. 8, 1986; 52 FR 7830, Mar. 13, 1987]

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 55 FR 31779, Aug. 3, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 346.1 Scope.

(a) An over-the-counter anorectal drug product in a form suitable for external (topical) or intrarectal (rectal) administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 212 unless otherwise noted.

§ 346.3 Definitions.

As used in this part:

(a) *Analgesic, anesthetic drug.* A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors.

(b) *Anorectal drug.* A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

(c) *Antipruritic drug.* A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors.

(d) *Astringent drug.* A drug that is applied topically (externally) to the skin or mucous membranes for a local and limited protein coagulant effect.

(e) *External use.* Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal.

(f) *Intrarectal use.* Topical application of an anorectal drug product to the mucous membrane of the rectum.

(g) *Keratolytic drug.* A drug that causes desquamation (loosening) and